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10/560,181

12/09/2005

Gitte Juel Friis

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EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

09/14/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/560,181 | Applicant(s) FRIIS ET AL. | |
| | Examiner SHANON A. FOLEY | Art Unit 1619 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-15,19,20,27,28 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-15,19,20,27,28 and 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 19, 20, 27, 28, 30, 32-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Cleary et al. (USPgPub 2003/0170308) for reasons of record.

Applicant argues that Cleary does not teach a device with a maximum absorption rate of 0.2 g/cm². Applicant argues that an absorption value of 0.223 g/cm² is indisputably greater than the required value of 0.2 g/cm². Applicant asserts that there is no authority to support the position of that the extra 0.023 taught by Cleary et al. is not considered significant.

Applicant's argument and a review of Cleary et al. have been fully considered, but are found unpersuasive. It is maintained that the absorption value of Cleary et al. of 0.223 g/cm² anticipates the required value of 0.2 g/cm². The required numerical value recited for absorption of the instant device is 0.2 g/cm². There are no values provided for the hundredths or thousandths positions after the decimal place, nor is there any discussion of any possible values that would be significant following 0.2 g/cm² in the disclosure. Therefore, the tenth position after the decimal place is the significant value. Any value provided in the hundredths and/or thousandths positions that are not significant enough for the tenths value of 0.2 to increase or mathematically rounded to 0.3 are insignificant. Therefore, it is maintained that the absorption

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value taught by Cleary et al. in Table 6 meets the instantly required absorption value of 0.2 g/cm². The authority relied on providing the rules for rounding numbers, in particular decimal tenths, may be found in any elementary grade school math study guide, such as those provided as an attachment to this Office action, found at the following web sites:

<http://www1.center.k12.mo.us/edtech/edm/4/htm> and <http://www.aaastudy.com/dec44cx2.htm>.

Applicant also argues that Cleary does not disclose a device that promotes moist wound healing.

However, this is contradicted by the teachings of Cleary et al., anticipating a maximum absorbency of wound exudates at a rate of 0.2 g/cm², see line 3 of Table 6 on page 20.

Applicant also asserts that the primary purposes of the Cleary dressing is to absorb moisture and teaches away from the use of a low absorbency device.

However, this assertion is also contradicted by the teachings of Cleary et al., anticipating a maximum absorbency of wound exudates at a rate of 0.2 g/cm², see line 3 of Table 6 on page 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. *supra*.

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The instant claims state that the device has a maximum absorption rate of 0.05 g/cm^2 , 0.75 g/cm^2 or 0.1 g/cm^2 .

See the teachings of Cleary et al. above. While Cleary et al. teach an absorption rate of 0.2 g/cm^2 in line 3 of Table 6 on page 20 for the hydrogel, Cleary et al. do not teach a maximum absorption rate of 0.05 g/cm^2 , 0.75 g/cm^2 or 0.1 g/cm^2 . However, Cleary et al. discuss disadvantages of adherence of absorbent material to wounds, rendering painful removal in the prior art, see paragraphs [0003-0005]. Cleary et al. also discuss the hydrophobic materials that have limited absorptive capacity, see paragraph [0037] for example. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the wound-covering material with a reasonable expectation of success for altering the amount of absorbency required for adequate protection and healing.

At the top of page 12 of the arguments, applicant states that "obviousness rejections can only be made with the use of impermissible hindsight".

While it is presumed that applicant intended to argue the opposite (since impermissible hindsight would be improper), applicant did not provide any support to concluding that improper hindsight reasoning was employed in the instant rejections. Nonetheless, in response to applicant's supposed argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170

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USPQ 209 (CCPA 1971). In the instant case, the knowledge gleaned to support the instant rejection is found solely in the teachings of Cleary et al., see excerpts cited. Therefore, impermissible hindsight is not an issue in the instant case.

Claims 8-15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. *supra* and Edgren et al. (US 6,245,357) for reasons of record.

In response to this rejection, applicant argues that the Office does not provide any reason for motivation for combining the oral dosage form of Edgren et al. with the “patch-like” device of Cleary et al.

Applicant’s arguments have been fully considered, but are found unpersuasive. The membrane system claimed by Edgren et al. in claim 28 is not limited to an oral dosage form (emphasis added). One of ordinary skill in the art at the time the invention was made would have been motivated to alter the quantity of analgesic drug released from a wound device, depending on the severity of the wound and the duration for pain relief required. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for altering the rate of analgesic release in the hydrogel of Cleary et al. in the membrane care system of Edgren et al. since both Cleary et al. and Edgren et al. deliver pain-relief agents through hydrogels, see the previous citations of Cleary et al. and claims 28 and 36-38 of Edgren et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-

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0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
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